



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,289	10/31/2003	David E. Wolf	205-011US2	1624
27791 7590 05/02/2007 ALLISON JOHNSON, P.A. LAKE CALHOUN EXECUTIVE CENTER 3033 EXCELSIOR BLVD., SUITE 467 MINNEAPOLIS, MN 55416			EXAMINER YANG, NELSON C	
			ART UNIT	PAPER NUMBER
			1641	
			MAIL DATE	DELIVERY MODE
			05/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/698,289

Applicant(s)

WOLF, DAVID E.

Examiner

Nelson Yang

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-90 is/are pending in the application.
- 4a) Of the above claim(s) 1,43,48-55,66-83,87 and 88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-42,44-47,56-65 and 84-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/19/04 2/5/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group III, claims 30-47 and 56-65 in the replay filed on November 9, 2006, and of the species of claim 47 and of claims 87-88 in the reply filed on February 8, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Response to Amendment

2. Applicant's amendment of claims 2-5, 7, 9, 11-16, 18, 19, 21-26, 28 is acknowledged and has been entered.
3. Applicant's addition of claims 84-90 is acknowledged and has been entered.
4. Claims 2-42, 44-47, 56-65, 84-90 are currently under examination

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 42, 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 42, 47 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See

Art Unit: 1641

MPEP § 2172.01. The omitted elements are: the steps that recite how to correct the intensity at the first and second wavelengths based on predetermined correction functions, as the functions have not been provided. Therefore, one of ordinary skill in the art would not know how to correct the intensity at the first and second wavelengths.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 30, 2, 3, 5-8, 14-19, 25, 26, 30-37, 41, 42, 44-47, 56-65, 84-86, 89-90 are rejected under 35 U.S.C. 102(b) as being anticipated by Empedocles et al. [US 2002/0031783].

With respect to claims 30, 56, Empedocles et al. teach a sensor comprising a polymeric matrix (para. 0081), multiple fluorophores (para. 0107), a membrane comprising a 7 micron layer of parylene (para. 0151), excitation sources (para. 0019), and multiple detectors, one for each separate fluorophore (para. 0107, 0145, fig. 2A-2E), and a processor coupled to the detectors (para. 0065) for determining the results of the assay (para. 0040).

Art Unit: 1641

9. With respect to claims 2, 3, 31, 32, 41, 58, 59, the sensor is capable of excitation and detecting ultraviolet light (para. 0102), and would therefore be capable of exciting and detecting light transcutaneously such as from under the skin.
10. With respect to claims 33, 57, the sensor has a networking connection (para. 0100), and therefore would be capable of transmitting signals to a remote location.
11. With respect to claims 5-6, 34, the sensor comprises 10 filters (para. 0116).
12. With respect to claims 7-8, 35-37, the sensor may comprise a system of dichroic mirrors (about 10) (para. 0116) for selectively transmitting signals (para. 0116, 0137).
13. With respect to claims 14, 15, the sensor comprises a processor (para. 0040) and has a networking connection (para. 0100), and therefore would be capable of transmitting signals to a remote location.
14. With respect to claims 16-17, 44-46, the sensor calculates an intensity and ratio among the various wavelengths to determine spectral characteristics (property of analyte) (para. 0089), such as by different concentrations (para. 0078).
15. With respect to claims 18, 19, the sensor comprises machine-readable code of program instructions (para. 0101).
16. With respect to claim 25, the sensor is capable of simultaneously imaging of identifiable spectra through a detection region (para. 0018).
17. With respect to claim 26, the sensor is capable of pulsing light with pulsed lasers (para. 0098).
18. With respect to claim 60, the sensor comprises a processor for determining the results of the assay (para. 0040).

Art Unit: 1641

19. With respect to claim 61, the sensor is capable of detecting spatially resolved labels (para. 0067).
20. With respect to claims 62-63, the sensor comprises a processor coupled to the detector (para. 0065), which one of ordinary skill in the art would know would comprise a clock and which would require an A/D converter to change the analog signal to a digital signal the processor would be capable of analyzing.
21. With respect to claim 64, the sensor has a networking connection (para. 0100), and therefore would be capable of transmitting signals to a remote location.
22. With respect to claim 65, the sensor calculates an intensity and ratio among the various wavelengths to determine spectral characteristics (property of analyte) (para. 0089), such as by different concentrations (para. 0078).
23. With respect to claim 84, the sensor may comprise light emitting diodes (para. 0098).
24. With respect to claims 85-86, the sensor comprises liquid crystal filters for scanning a surface (para. 0109).
25. With respect to claims 89, 90, the sensor may comprise a diode array or CCD (para. 0099).
26. Claims 30, 4, 9-19, 22, 24, 28, 29, 38-40, 45, 46, 56, 57, 60-65, 89 are rejected under 35 U.S.C. 102(a) and under 35 U.S.C. 102(e) as being anticipated by Zenhausern [US 2002/0094531].

With respect to claims 30, 56, Zenhausern teaches a sensor comprising a polymeric matrix (para. 0077), multiple fluorophore markers (para. 0021) comprising four spectrally resolvable dyes (para. 0073), a membrane comprising (para. 0077), a laser (excitation source)

Art Unit: 1641

(para. 0077), and a multiple sensor array as the detector (para. 0025), and an electronic processing means (para. 0077) and database software for archiving and graphical display (para. 0077).

27. With respect to claims 4, 33, 57, Zenhausern teaches a transmission means capable of transmitting a signal between the multivariate detector and a data acquisition system (para. 0051), wherein the communications method may be wireless (para. 0059).

28. With respect to claims 9-11, Zenhausern teaches optical fiber as part of the sensor (para. 0069), which would render it operatively connected to the detector and excitation source as it is part of the sensor.

29. With respect to claims 12, 13, Zenhausern teaches a pump that carries the analyzed sample (with fluorophores) to a waste reservoir (para. 0080), which would render the fluorophores mobile.

30. With respect to claim 14, Zenhausern teaches database software for archiving and graphical display (para. 0077).

31. With respect to claim 15, Zenhausern teaches a transmission means capable of transmitting a signal between the multivariate detector and a data acquisition system (para. 0051).

32. With respect to claims 16-19, Zenhusern teaches comparing the analysis of the signals at several wavelengths with the properties of the analyte as a result of surface interactions (para. 0034), such as changes in concentration (claim 13).

33. With respect to claim 22, Zenhusern teaches that the sensor can detect proteins (para. 0026).

Art Unit: 1641

34. With respect to claim 24, Zenhusern teaches that the sensor is semiconductor based (para. 0040) and located on a substrate (para. 0077), which would make the substrate a semiconductor wafer upon which the detectors would be located.

35. With respect to claims 25, 27, Zenhusern teaches a multiplexer for simultaneous analysis of the data (para. 0090), and which would be capable of phase locking the counting of signals at the detectors.

36. With respect to claims 28, 29, Zenhusern teaches a pump (para. 0080), which would be capable of drawing interstitial fluid or blood.

37. With respect to claims 38-40, Zenhusern teaches optical fibers as part of the sensor (para. 0069), which would render it operatively connected to the detector and excitation source as it is part of the sensor.

38. With respect to claims 45, 46, Zenhusern teaches comparing the analysis of the signals at several wavelengths with the properties of the analyte as a result of surface interactions (para. 0034), such as changes in concentration (claim 13).

39. With respect to claims 60, 61, Zenhusern teaches an electronic processing means (para. 0077) and database software for archiving and graphical display (para. 0077).

40. With respect to claim 62, Zenhusern teaches a multiplexer which would convert the signal from analog to digital before outputting the data to the computer (para. 0090).

41. With respect to claim 63, the computer taught by Zenhusern would comprise a clock (para. 0090).

Art Unit: 1641

42. With respect to claim 64, Zenhausern teaches a transmission means capable of transmitting a signal between the multivariate detector and a data acquisition system (para. 0051), wherein the communications method may be wireless (para. 0059).

43. With respect to claim 65, Zenhausern teaches comparing the analysis of the signals at several wavelengths with the properties of the analyte as a result of surface interactions (para. 0034), such as changes in concentration (claim 13).

44. With respect to claim 89, Zenhausern teaches a multiple sensor array as the detector (para. 0025).

Claim Rejections - 35 USC § 103

45. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

46. Claims 20, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Empedocles et al. [US 2002/0031783] in view of Walsh et al. [US 2002/0193671].

With respect to claims 20, 23, Empedocles et al. teach a sensor comprising a polymeric matrix (para. 0081), multiple fluorophores (para. 0107), a membrane comprising a 7 micron layer of parylene (para. 0151), excitation sources (para. 0019), and multiple detectors, one for each separate fluorophore (para. 0107, 0145, fig. 2A-2E), and a processor coupled to the detectors (para. 0065) for determining the results of the assay (para. 0040). Empedocles et al. fail to teach that the sensor detects glucose.

Walsh et al., however, do discuss the monitoring of glucose levels, wherein the signal from the detector may be used as an input to an insulin pump (para. 0091) for delivering insulin to a patient, and teach that the detection and quantification of blood glucose levels substantially lessens the disease's symptomatic complications (para. 0004).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the device of Empedocles et al. to measure glucose as suggested by Walsh et al., in order to lessen the symptomatic complications from patients with diabetes.

47. Claims 20, 21, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Empedocles et al. [US 2002/0031783] in view of Martin et al. [US 2002/0016535].

With respect to claims 20, 23, Empedocles et al. teach a sensor comprising a polymeric matrix (para. 0081), multiple fluorophores (para. 0107), a membrane comprising a 7 micron layer of parylene (para. 0151), excitation sources (para. 0019), and multiple detectors, one for each separate fluorophore (para. 0107, 0145, fig. 2A-2E), and a processor coupled to the detectors (para. 0065) for determining the results of the assay (para. 0040). Empedocles et al. fail to teach that the sensor detects glucose, provides an alarm, or administers insulin.

Martin et al., however, teach a glucose sensor incorporated with an insulin pump (para. 0061) in order to provide a glucose measuring and insulin delivery system that allow the return of near normal functioning of the body (para. 0061).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the device of Empedocles et al. to measure glucose as suggested by

Art Unit: 1641

Martin et al., in order to allow the return of normal function to the bodies of patients with diabetes.

48. With respect to claim 21, the sensor further teach an alarm when a glucose levels are becoming to high or low or when there is no response (para. 0058), which ensures that the sensor is working properly (para. 0053).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated an alarm in the device of Empedocles et al., as suggested by Martin et al., in order ensure that the sensor is working properly.

49. Claims 20, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zenhausern [US 2002/0094531] in view of Walsh et al. [US 2002/0193671].

With respect to claims 20, 23, Zenhausern teaches a sensor comprising a polymeric matrix (para. 0077), multiple fluorophore markers (para. 0021) comprising four spectrally resolvable dyes (para. 0073), a membrane comprising (para. 0077), a laser (excitation source) (para. 0077), and a multiple sensor array as the detector (para. 0025), and an electronic processing means (para. 0077) and database software for archiving and graphical display (para. 0077). Zenhausern fails to teach that the sensor detects glucose, provides an alarm, or administers insulin.

Martin et al., however, teach a glucose sensor incorporated with an insulin pump (para. 0061) in order to provide a glucose measuring and insulin delivery system that allow the return of near normal functioning of the body (para. 0061).

Art Unit: 1641

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the device of Zenhausern to measure glucose as suggested by Martin et al., in order to allow the return of normal function to the bodies of patients with diabetes.

50. With respect to claim 21, the sensor further teach an alarm when a glucose levels are becoming to high or low or when there is no response (para. 0058), which ensures that the sensor is working properly (para. 0053).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated an alarm in the device of Zenhausern, as suggested by Martin et al., in order ensure that the sensor is working properly.

Conclusion

51. No claims are allowed.


52. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang
Patent Examiner
Art Unit 1641


LONG V. LE 04/27/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600